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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
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JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/24/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/762,630

Applicant(s)

EMBIL ET AL.

Examin r

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this c mmunication appears on the cover sheet with th c rrespondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on the amendment of 24 JUN 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 19-38 are pending.
2. Claims 19-38 are rejected.

### ***Response to Arguments***

3. Applicants' arguments filed June 24, 2003 have been fully considered but they are not persuasive. Applicants make the following arguments. First, applicants argue that Jain et al. teach away from the present anhydrous invention because Jain et al. required the presence of water. Next, applicants allege that Kruse et al. require the use of water to create a lotion.

4. First, applicants argue that Jain et al. teach away from the present anhydrous invention because Jain et al. required the presence of water. This argument is not persuasive because Jain et al. specifically teach that it is already known in the art that, "the highly hydrophobic drug" of nimesulide (see page 2, lines 15-17 and lines 27-30). Consequently, "[i]t is an object of the present invention to provide a therapeutic composition containing nimesulide in combination with other compounds which alter the hydrophobic property of nimesulide and a process for the manufacture thereof", (see page 2, lines 49-50). In addition, Jain et al. teach that a percutaneous enhancer may be "preferably a C<sub>12-24</sub> mono or polyunsaturated fatty acid, especially oleic acid, (see page 4, lines 15-17). Jain et al. further teach the skilled artisan of specifically using a

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percutaneous enhancer of the monoglyceride of "Glycrol monooleate" as well as the gelling agent of "hydroxypropyl cellulose.", (see page 4, lines 44-50). In fact, Jain et al. specifically teach that the composition may also include a vehicle/base, (see from page 4, line 56 to page 5, line 1). Furthermore, Jain et al. teach that, "[w]ater in varying concentration[s]" is optional in that it may be added, (see page 5, line 2).

5. Next, applicants allege that Kruse et al. require the use of water to create a lotion. Kruse et al. teach when a lotion is to be made, "[t]he balance of the lotion is water or a C<sub>2</sub> or C<sub>3</sub> alcohol", (see column 116, lines 42-43). In addition, Kruse et al. disclose that creams may also, "contain from 5% to 50% of an emollient . . . and the remainder is water or other suitable non-toxic carriers.", (see column 116, lines 62-65). Furthermore, Kruse et al. teach of a variety of emollients in amounts ranging from 0.1 to 50% w/w, (see columns 113-116). For these reasons, the prior art reference of Kruse et al. make the instantly claimed invention obvious to one having ordinary skill in the art.

### ***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. The rejection of claims 18-3 under 35 U.S.C. 103(a) as being unpatentable over Jain et al. of EP 812,587 A1 possessing a publication date of December 17, 1997 is maintained and repeated for both the above-stated and reasons of record. Jain et al. teach of a non-staining composition of nimesulide, which contains monoglycerides, such

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as glycerol monooleate, in an amount ranging from 0.5 % to 12 % by weight, (see abstract and page 4, lines 4-13 and 42-43 and page 5, lines 14 and 15). Moreover, Jain et al. teach that it is well known in the art that nimesulide possesses both anti-inflammatory and analgesic properties, (see page 2, lines 5-20). Also, Jain et al. teach of including the presence of hydroxypropyl cellulose as a gelling agent, (see page 4, lines 44-52). Jain et al. also teach of methods of making compositions that contain nimesulide, (see page 4, lines 1-13). In the steps, Jain et al. teach of stirring and mixing the nimesulide in order to dissolve the nimesulide. Jain et al. also teach of combining the surfactants, in particular glycerol monooleate, along with the nimesulide mixture by obvious laboratory synthesis reaction techniques, such as stirring, mixing, changing parameters such as pH, pressure or temperature. Furthermore, Jain et al. disclose that these therapeutic compositions may be used as a gel, emulsion, cream, solution, ointment or aerosol, (see page 5, lines 16-29). Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), see also *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). It would have been obvious to one having ordinary skill in the art to optimize the range of the glyceryl monoolein in order to improve the surfactant properties of the sparingly soluble nimesulide. In addition, it is within the purview of the skilled artisan to utilize these topical compositions that contain nimesulide for ailments

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that are alleviated or treated with a compound that has anti-inflammatory and analgesic properties. In addition, the skilled artisan would have been motivated to formulate compositions of nimesulide with the glycerin monooleate by synthesis techniques that are known in the art, such as stirring, mixing, changing parameters such as pH, pressure or temperature. Accordingly, it would have been obvious to the skilled artisan to perform well known synthesis techniques in order to make formulations that contain nimesulide along with the glycerin monooleate

8. The rejection of claims 18-25 and 30-38 under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. of U.S. Patent No. 5,744,458 is maintained and repeated for both the above-stated and reasons of record. Kruse et al. teach of a topical composition, which contains nimesulide, (see column 121, line 48) and glyceryl mono-fatty acid esters, (see column 115, lines 50-64). In addition, Kruse et al. teach that the glyceryl mono-fatty acid esters are present in the composition in from 1% to 50 %, (see column 114, lines 34-36 and 39-42). Although the prior art reference of Kruse et al. do not specifically recite the glyceryl monoolein, this obviously falls within the meaning a glycerol mono-fatty acid, and thus is in the purview of the skilled artisan. For these reasons, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any fatty acid, including oleic acid, to be usable along with an active agent such as nimesulide. In addition, it is within the purview of the skilled artisan to utilize these topical compositions that contain nimesulide for ailments that are alleviated or treated with a compound that has anti-inflammatory and analgesic

properties due to the fact that it is known in the art that nimesulide possesses anti-inflammatory and analgesic properties.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

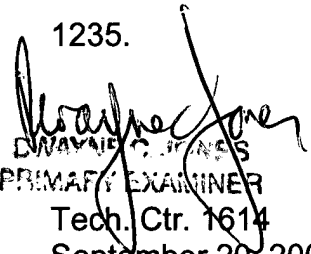
10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
DWAYNE C. JONES  
PRIMARY EXAMINER  
Tech. Ctr. 1614  
September 20, 2003